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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

[redacted]

HIKMA PHARMACEUTICALS USA INC.,	:	Honorable
Plaintiff,	:	Civil Action No.
v.	:	
	:	**COMPLAINT**
AMARIN PHARMA, INC., AMARIN PHARMARCEUTICALS IRELAND LIMITED, AND AMARIN CORPORATION PLC,	:	**JURY TRIAL DEMANDED**
Defendants.	:	

Plaintiff, Hikma Pharmaceuticals USA Inc. ("Hikma") brings this antitrust lawsuit against Defendants, Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Amarin Corporation plc (collectively, "Amarin" or "Defendants"), by and through the undersigned attorneys and alleges as follows:

INTRODUCTION

1. This is an action under the Sherman Act and New Jersey law arising out of Amarin's anticompetitive conduct to prevent, delay, and frustrate generic competition to its

branded Vascepa® (icosapent ethyl) product. Amarin deliberately and meticulously locked up the supply of active pharmaceutical ingredient ("API") icosapent ethyl, in excess of its own needs, in order to reap excessive monopoly profits by thwarting generic competitors from timely bringing affordable and more widely available products to market.

2. Vascepa is a prescription drug used, among other things, to lower harmful triglycerides, a type of lipid, once they get to a very high level. As Amarin's only marketed product approved by the U.S. Food and Drug Administration ("FDA"), Vascepa sales drive the success of the company.

3. From its launch in 2012, Vascepa experienced rise in sales and popularity. In 2013, Amarin reported revenues of more than $26 million, Amarin Corp. Plc., Annual Report (Form 10-K) (Feb. 27, 2014), and by 2020 this soared to $607 million, Amarin Corp. Plc, Annual Report (Form 10-K) (Feb. 25, 2021), for an increase of approximately 2,204% or approximately 315% increase by year. Amarin projected for this growth to continue as well, stating, "VASCEPA total net revenue will grow to reach multiple billions of dollars." Amarin Corp., *Amarin Receives FDA Approval of Vascepa® (Icosapent Ethyl) to Reduce Cardiovascular Risk*, (Dec. 13, 2019 4:48 PM EST), https://investor.amarincorp.com/news-releases/news-release-details/amarin-receives-fda-approval-vascepar-icosapent-ethyl-reduce.

4. From Vascepa's launch in the United States through 2020, Vascepa was "prescribed over eight million times" and was "covered by most major medical insurance plans." Amarin Corp., *Vascepa® (Icosapent Ethyl) Shows Significant Cardiovascular Risk Reduction in People with Diabetes in Prespecified and Post Hoc Subgroup Analyses of Landmark Reduce-IT® Study*, (June 15, 2020 7:00 AM EDT), https://investor.amarincorp.com/news-releases/news-release-details/vascepar-icosapent-ethyl-shows-significant-cardiovascular-risk#.

5. This one-product company hit the jackpot, until the threat of generic competition became real. For Amarin, it is Vascepa-or-bust. The company has no other products or a meaningful pipeline behind Vascepa. *See* Leila Hawkins, *Pharma IQ speaks to Amarin about its unique approach to treating cardiovascular disease and having a country-by-country strategy* (Nov. 30, 2022), https://www.pharma-iq.com/market-access/interviews/pharma-company-with-a-build-as-you-go-approach (quoting Laurent Abuaf, the "SVP and President for Europe at Amarin" as stating that Amarin is "a one-product company, which means it is a high risk for [Amarin]"); Christopher Crocker *Amarin's Vascepa: Reject the Noise and Accept the Facts*, Seeking Alpha (Nov. 28, 2018 9:30 AM ET), https://seekingalpha.com/article/4225047-amarins-vascepa-reject-noise-and-accept-facts (after the Vascepa clinical studies were over, Amarin's then-"CEO John Thero said Amarin plans to completely cut R&D").

6. Having everything to lose, Amarin pulled out no stops—embarking on a long, illegal anticompetitive strategy to prevent, delay, and frustrate generic competition and maintain its monopoly power and prices for Vascepa.

7. Amarin undertook this anticompetitive scheme through a series of exclusive, or de facto exclusive, agreements with different API suppliers. In exchange for agreeing to purchase certain minimum amounts, these API suppliers agreed not to supply API to any other companies—including Hikma or any other generic manufacturer. What's more, under some (if not all) of the agreements, if Amarin cannot satisfy the minimum purchase requirement, Amarin agreed to make a cash payment to maintain exclusivity and keep that API supplier from contracting with another company, like Hikma. Amarin thus paid cash to preserve its monopoly.

8. Amarin's exclusive agreements with these API suppliers can only be explained as a calculated effort to ensure no other company could robustly manufacture the generic version of

its product. Contracting with numerous, exclusive API suppliers is inconsistent with the well-established industry practice of branded-drug manufacturers having only one or two non-exclusive API suppliers (even if more are available) due to cost and/or quality issues. Deviating from industry practice is especially unusual for a drug that has had no known supply issues. Indeed, Amarin had publicly touted its vast API supply.

9. The threat to Amarin's success materialized, in September 2016 Hikma filed an application with the FDA seeking approval to launch a generic version of Vascepa. In response, Amarin sued Hikma (and other generic pharmaceutical companies) for patent infringement. At this time, the FDA had approved Vascepa solely for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Under FDA regulations, Amarin's patent lawsuit triggered an automatic stay on FDA approval of generic competition for a certain amount of time. In late 2019, the FDA approved a second indication for Vascepa—for use as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride levels and other risk factors.

10. On March 30, 2020, after a bench trial, the United States District Court for the District of Nevada found Amarin's patents invalid due to obviousness. *Id.* at ECF 78. The court relied on several prior-art references to invalidate the patents and Amarin's own admission that "[t]he safety and efficacy of using prescription omega-3 in combination with a statin has been well-established." *Amarin Pharm. Inc. v. Hikma Pharms. USA Inc.*, 449 F. Supp. 3d 967, 986 (D. Nev. Mar. 30, 2020) (internal quotation marks and citation omitted).

11. On May 22, 2020, Hikma received FDA approval to launch its generic version of Vascepa for the first FDA-approved indication—i.e., use as an adjunct to diet to reduce triglyceride

levels in adult patients with severe hypertriglyceridemia. At the time, Hikma was the only company with final FDA approval to launch a generic version of Vascepa. Having invalidated Amarin's patents and received final regulatory approval, Hikma had every incentive to launch its product quickly at full commercial capacity.

12. As the first generic drug manufacturer eligible for marketing exclusivity, Hikma worked diligently to launch its product—including, but not limited to, working to secure an API supplier. During the FDA-approval process, Hikma secured a limited amount of API supply for testing purposes without an issue. However, as Hikma prepared for commercial launch in competition with Amarin, it quickly became clear that Amarin had carefully and purposefully crafted a contractual web with API suppliers designed to prevent, delay, and frustrate generic manufacturers' access to API, increase their API costs, and limit their supply—thereby thwarting competition from generic competition on its single drug.

13. One does not have to infer Amarin's motive for multiple exclusive supply agreements because its then-CEO made Amarin's anticompetitive goals explicit: "***Amarin's goal [is] to protect the commercial potential of Vascepa*** to beyond 2030 through a combination of patent protection, regulatory exclusivity, trade secrets and ***by taking advantage of manufacturing barriers to entry***." Amarin Corp., *Amarin Announces Approval of Supplemental New Drug Application for Chemport as Additional Vascepa(R) Active Pharmaceutical Ingredient Supplier* (Apr. 18, 2013), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-approval-supplemental-new-drug-application (emphases added).

14. Amarin's well-designed anticompetitive scheme has, in fact, created "barriers to entry"—delaying generic competition and making API supply more costly, thus limiting generic manufacturers' ability to fully compete, including with lower prices. Even though Hikma

diligently and timely reached out to API suppliers, those efforts were blocked by Amarin's exclusive or de facto exclusive agreements. Hikma was left with a single API supplier option that had limited capacity and high prices.

15. Hikma did not launch its generic product until November 4, 2020, and that launch was not the commercial launch Hikma expected. But for Amarin's substantial foreclosure of API supply, Hikma would have had a more robust launch with lower API costs and thus lower prices.

16. There is no legitimate business reason for Amarin's conduct, which can be explained only as an anticompetitive strategy to erect "entry barriers" and to delay generic competition to its branded Vascepa. These efforts harm Hikma and consumers.

THE PARTIES

17. Hikma Pharmaceuticals USA Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 200 Connell Drive, Berkeley Heights, New Jersey 07922.

18. Upon information and belief, Amarin Pharma, Inc. is a company organized under the laws of Delaware with its principal place of business at 440 Route 22, Suite 330, Bridgewater, NJ 08870.

19. Upon information and belief, Amarin Pharmaceuticals Ireland Limited is a company incorporated under the laws of Ireland with registered offices at 88 Harcourt Street, Dublin 2, Dublin, Ireland.

20. Upon information and belief, Amarin Corporation plc is a company incorporated under the laws of England and Wales with principal executive offices at 77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, Dublin 2, Ireland.

JURISDICTION AND VENUE

21. This action arises under the antitrust laws of the United States, including Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, Sections 4 and 16 of the Clayton Act, 15 U.S.C §§ 15(a) and 26, the New Jersey Antitrust Act, N.J. Stat. § 56:9, and New Jersey common law.

22. The actions complained of occurred in, and substantially affected, interstate commerce. Specifically, Amarin is engaged in interstate commerce and in activities substantially affecting interstate commerce. Amarin's conduct alleged herein has a substantial effect on interstate commerce. Amarin purchases icosapent ethyl API in interstate commerce, and Amarin's products are marketed and sold in all states and territories of the United States. Drug wholesalers and, ultimately, patients across the country purchase Amarin's drug, Vascepa.

23. Amarin Pharma, Inc. may be found in, transacts business in, is headquartered in, and is subject to personal jurisdiction in the District of New Jersey.

24. Amarin Pharmaceuticals Ireland Limited transacts business in and is subject to personal jurisdiction in the District of New Jersey.

25. Amarin Corporation plc transacts business in and is subject to personal jurisdiction in the District of New Jersey.

26. This Court has subject-matter jurisdiction based on 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. §§ 15 and 26. This Court has supplemental subject-matter jurisdiction over the New Jersey state-law claims pursuant to 28 U.S.C. § 1367(a).

27. The violations of law alleged in this Complaint took place, in part, and have injured Hikma in this judicial district. Venue is therefore proper in the District of New Jersey pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391.

STATEMENT OF FACTS

A. Regulatory Framework

28. Under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the "Hatch-Waxman Act," manufacturers that create a new drug must obtain approval from the FDA to sell the product by filing a New Drug Application ("NDA"). An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. The overarching purpose of the Hatch-Waxman Act is to balance the preservation of brand pharmaceutical companies' incentives to innovate with the public interest in access to lower-cost, high-quality generic drugs through the creation of a carefully calibrated regulatory framework.

29. When the FDA approves a brand pharmaceutical manufacturer's NDA, the manufacturer may list in *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book") certain patents that the manufacturer asserts could reasonably be enforced against a manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents.

30. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability because it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

31. In addition, to achieve the goal of "get[ting] generic drugs into the hands of patients at reasonable prices—fast," *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (internal quotation marks omitted) (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)), the Hatch-Waxman Act creates a procedure for generic manufacturers to file

Abbreviated New Drug Applications ("ANDAs") with the FDA. An ANDA filer has to show that its drug is bioequivalent to the "reference listed drug," typically the branded drug, to demonstrate that the generic product has the same or comparable safety and efficacy as the reference-listed drug.

32. If an ANDA applicant seeks FDA approval to sell a generic drug before the expiration of the patents listed in the Orange Book as covering the drug, the ANDA must contain one of four certifications:

a. That no patent for the brand has been filed with the FDA (a paragraph I certification);

b. That any patent(s) for the brand has/have expired (a paragraph II certification);

c. That any patent(s) for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date (a paragraph III certification); or

d. That any patent(s) for the brand is/are invalid or will not be infringed by the generic manufacturer's proposed product (a paragraph IV certification).

21 U.S.C. § 355(j)(2)(A)(vii).

33. If a generic manufacturer files a paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by timely suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA-filer (which would enable the manufacturer to market and sell its product) until the earlier of (a) the passage of two-and-a-half years (30 months), or (b) the issuance of a decision by a court that the asserted claims of the patent(s) at issue are invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). This period is commonly called a 30-month Hatch-Waxman stay or 30-month stay. Until one of those conditions

occurs, the FDA may grant only tentative approval, meaning the ANDA meets all regulatory requirements and is approvable but for the 30-month stay. Alternatively, the brand/patent holder can choose to sue the generic applicant after 45 days, including waiting until the generic has launched its product. But in that event, the brand cannot take advantage of the 30-month stay of FDA approval and must instead satisfy the showing required to obtain a preliminary or permanent injunction to prevent the generic launch.

34. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Act grants the first paragraph IV generic manufacturer ANDA filer (the "first-filer") a 180-day exclusivity period to market the generic version of the drug; the FDA may not grant final approval to any other generic manufacturer's ANDA for the same branded drug during that time. 21 U.S.C. §§ 355(j)(5)(B)(iv), (D). That is, with certain statutory exceptions, when a first-filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book covering the branded drug are either invalid or not infringed by the generic, the FDA cannot approve a later generic manufacturer's ANDA until that first-filer's generic has been on the market for 180 days.

35. The Hatch-Waxman Act also encourages generic manufacturers to seek approval of generic products for uses that do not infringe valid and enforceable patents. The Act recognizes that a generic-drug manufacturer may infringe one (patented) method of use without infringing another and encourages generics to "carve out" of the generic-product label would-be infringing uses (i.e., an FDA-approved indication for a method of treatment covered by a patent) to bring noninfringing products to market quickly.

36. To carve out a non-infringing use, an ANDA applicant may submit what is referred to as a "Section viii statement" along with a redacted product label. A Section viii statement asserts

that the generic manufacturer will market the drug for one or more FDA-approved indications (i.e., methods of use) not covered by the brand's valid and enforceable patents. 21 U.S.C. § 355(j)(2)(A)(viii). If an ANDA applicant files a Section viii statement and submits a product label that "carves out" the patented method of use or indication, the patent claiming the protected method of use will not serve as a barrier to ANDA approval.

37. Typically, the Hatch-Waxman Act requires that an ANDA contain "information to show that the labeling proposed for the new [generic] drug is the same as the labeling approved for the listed drug[.]" 21 U.S.C. § 355(j)(2)(A)(v). However, FDA regulations also recognize that, by submitting a Section viii statement, an ANDA applicant may omit from the proposed labeling a method of use protected by a listed patent, and therefore need not seek approval for that use. *See* 21 CFR § 314.94(a)(8)(iv) ("Such differences between the applicant's proposed labeling and labeling approved for the reference listed drug may include … omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act."); *see also* 21 CFR § 314.127(a)(7). As the Supreme Court of the United States has recognized, "[t]he statutory scheme, in other words, contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 415 (2012); *see also Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004) (upholding generic manufacturer's right to file a Section viii statement and carve out from labeling method-of-use information protected by a patent); *TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 73 (D.D.C. 2003), *aff'd sub nom. Purepac Pharm. Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004) (same).

38. The Supreme Court has explained that the Hatch-Waxman Act, and particularly 21 U.S.C. § 355(j)(2)(A)(viii), authorizes the FDA to approve the marketing of a generic drug for a

particular unpatented use, and under this statutory scheme, a patented use that does not appear on the generic-product label will not foreclose marketing a generic drug for other unpatented uses.

B. Supply and Use of API

39. All drugs are made up of two core components: (i) the active pharmaceutical ingredient ("API"), which is the biologically active component of a drug product and the central ingredient, and (ii) the excipient(s), the other ingredient(s) that, although inactive, may perform a variety of other functional roles in the drug. The API is the part of any drug that produces the intended effects. Excipients are chemically inactive substances in the drug, such as lactose or mineral oil.

40. The API in Vascepa is icosapent ethyl. It is a highly purified ethyl ester of eicosapentaenoic acid, a type of omega-3 fatty acid. Vascepa is the only FDA-approved branded purified icosapent ethyl product.

41. Brand and generic pharmaceutical manufacturers ordinarily purchase the API for their drugs from API suppliers. Drug manufacturers then combine the API with inactive ingredients and formulate the drugs into final dosage forms. The API for a branded drug and its generic equivalent is the same.

42. APIs are subject to stringent regulations and oversight by the FDA. To sell an API in the United States, the API supplier must file a Drug Master File ("DMF") with the FDA. The DMF provides confidential and detailed information about, among other things, the facilities and processes used to manufacture, process, package, and store the API.

43. In its application for FDA approval, a manufacturer must identify its API supplier and that supplier's DMF. More than one manufacturer can reference the DMF of the same API supplier. As part of its review of an NDA or ANDA, the FDA performs a complete review of the

technical information contained in the DMF referenced therein, including, among other things, inspecting the API supplier's facilities described in the DMF.

44. If a manufacturer wants or needs to change its API supplier for a drug, it must file a supplement with the FDA referencing the new API supplier's DMF and submit data for drug batches using the new supplier's API. The manufacturer may only market its drug using the new supplier's API if the FDA approves the change. FDA review and approval of the change in API supplier can take six months or more.

45. To avoid delays in the process and to keep costs lower, generic-drug manufacturers typically seek to use API from suppliers that already have a DMF on file, rather than partnering with API suppliers that have not yet filed a DMF. It is common for generic and branded manufacturers to use the same API supplier.

46. Because of the costs involved in qualifying an API supplier, as well as the need to continue to ensure quality control by the API supplier, it is industry practice for both brand and generic drug manufacturers to use only one or two API suppliers to support a drug application. It is unusual and contrary to industry practice for a brand or generic manufacturer to have multiple, exclusive API supply contracts, or for a manufacturer to acquire significant excess API supplies, due to, among other things, the costs of acquisition and storage and quality control issues.

47. Generic versions of branded drugs contain the same API as the brand-name drug and are determined by the FDA to be just as safe and effective as their brand counterparts. Because the branded drug and its generics are therapeutically equivalent, the primary basis for competition between a branded product and its generic version, or between multiple generic versions, is price.

48. Without generics in the market, the manufacturer of a branded drug has a monopoly—every sale of the product, and the accompanying profit, benefits the branded-drug

manufacturer. Without generic competition, branded-drug manufacturers can, and routinely do, sell their drug for far more than the marginal cost of production, generating profit margins above 70%.

49. When a generic equivalent enters the market, however, absent other market complexities it often quickly captures 80% or more of the unit sales from the branded drug. When generic entry occurs, the branded-drug manufacturer loses most of the unit sales; the generic manufacturer sells most of the units but at reduced prices, delivering enormous savings to drug purchasers, insurance companies and patients. When multiple generics compete in the market, that competition drives prices even lower.

C. Amarin's Vascepa® Product

50. Upon information and belief, Amarin holds approved NDA No. 202057 for Vascepa. Vascepa is available in two strengths: 1g and 500mg. There are currently two approved indications for Vascepa: (a) as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and (i) established cardiovascular disease or (ii) diabetes mellitus and two or more additional risk factors for cardiovascular disease ("the CV Indication"); and (b) as an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia ("the Very High TG Indication").

51. Vascepa was approved for treatment of the Very High TG Indication on July 26, 2012. Vascepa was approved for treatment of the CV Indication on December 13, 2019.

52. Upon information and belief, Amarin has listed at least 61 different patents in the FDA Orange Book in connection with Vascepa. Of those 61 patents, Amarin caused several to be listed that relate to the Very High TG Indication, including, among others, U.S. Patent Nos.

8,293,728, 8,318,715, 8,357,677, 8,367,652, 8,377,920, 8,399,446, 8,415,335, 8,426,399, 8,440,650, and 8,518,929.

53. Amarin listed several other patents in the Orange Book relating to the CV Indication, including, among others, the '537, '077, and '861 patents.

D. Amarin Enters Exclusive Supply Agreements Designed to Harm Competition

54. Based on information and belief, Amarin entered into exclusive agreements with numerous API suppliers—including, but not limited to, Nisshin Seifun Group Inc. ("Nisshin"), BASF SE (formerly Equateq Ltd.) ("BASF"), Chemport, Inc. ("Chemport"), Novasep Inc. ("Novasep"), and Slanmhor Pharmaceutical Inc. ("Slanmhor")—to maintain supply exclusivity and exclude or delay potential competitors from the market. This anticompetitive conduct has allowed Amarin to maintain artificially high prices for its product and to delay, hinder, and frustrate robust generic competition.

55. Amarin entered into the first of these exclusive API supply agreements with Japan-based Nisshin in November 2010. Upon information and belief, at the time Amarin contracted with Nisshin, Nisshin had an approved DMF to manufacture the API icosapent ethyl on file with the FDA, and Nisshin was the API supplier included in Amarin's NDA. The terms of that agreement prohibit Nisshin from selling API for commercial use to any competitor. Amarin initially purchased all its API needs from Nisshin.

56. Approximately four months later, in March 2011 (more than a year before Vascepa launched), Amarin signed a second exclusive supply agreement with Chemport. Upon information and belief, when Amarin contracted with Chemport, Chemport had an approved DMF to manufacture the API icosapent ethyl on file with the FDA. Like the Nisshin agreement, under the terms of that agreement, Chemport was prohibited from supplying any competitors so long as Amarin met certain minimal purchase requirements. Amarin Corp. plc Quarterly Report (Form

10-Q), at 9 (Aug. 9, 2011) ("Following FDA approvals of [Vascepa], both agreements [with Equateq and Chemport] include annual purchase levels to enable Amarin to maintain exclusivity with each respective supplier, and to prevent potential termination of the agreements.").

57. A mere three months later, in June 2011 (well before Vascepa launched), the BBC reported that Amarin had entered into a third exclusive supply agreement with Scotland-based Equateq Ltd. ("Equateq"). *Drug firm Equateq secures big US order*, BBC News (July 4, 2011), https://www.bbc.com/news/uk-scotland-scotland-business-14013747. Upon information and belief, when Amarin contracted with Equateq, Equateq had an approved DMF to manufacture the API icosapent ethyl on file with the FDA. Like Amarin's other agreements, Equateq was prohibited from supplying competitors if Amarin met minimum purchase requirements. Amarin revealed to investors in August 2011 that the minimum purchase commitment was intended to prevent Equateq from selling Vascepa API to any potential competitor of Amarin: "Following FDA approvals of [Vascepa], both agreements [with Equateq and Chemport] include annual purchase levels to enable Amarin to maintain exclusivity with each respective supplier, and to prevent potential termination of the agreements." Amarin Corp. plc Quarterly Report (Form 10-Q), at 9 (Aug. 9, 2011). To lock in Equateq's exclusivity, Amarin also paid Equateq a $1 million "commitment fee" in May 2011. *Id.* Equateq was acquired by BASF in May 2012. *BASF completes omega-3 portfolio with Equateq buy*, NUTRAingredients.com (May 8, 2012), https://www.nutraingredients.com/Article/2012/05/09/BASF-completes-omega-3-portfolio-with-Equateq-buy.

58. Six months later, in December 2012, Amarin announced it had entered into additional exclusive supply agreements with Canada-based Slanmhor and Novasep, "the world's largest supplier of concentrated omega-3 fatty acid products." Amarin Corp. PLC, "Amarin

Announces Additional Vascepa(R) (Icosapent Ethyl) Supplier," (Dec. 11, 2012), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-additional-vascepar-icosapent-ethyl-supplier. Upon information and belief, when Amarin contracted with these companies, they had an approved DMF to manufacture the API icosapent ethyl on file with the FDA. Amarin explained that "Slanmhor, through exclusive agreements, is collaborating with DSM/ONC for the supply of intermediate omega-3 oil, and Novasep, a global leader in purification technologies and API manufacturing." *Id.* Together, the companies would work to "reliably source Vascepa." *Id.*

59. Because Amarin's 2012 FDA approval was based solely on Nisshin as its approved API supplier, Amarin had to seek supplemental approval from the FDA to use any of the other API suppliers with whom Amarin had entered exclusive dealing arrangements. Having already a sufficient supply of API, Amarin did not rush to file supplemental new drug applications ("sNDAs") adding these suppliers.

60. In December 2012, Amarin submitted an sNDA for FDA approval to add Chemport as an API supplier—that application was submitted more than a year after having contracted with Chemport in March 2011. Amarin Corp. PLC, *Amarin Announces Submission of Supplemental New Drug Application for Chemport, Inc. as an Additional Vascepa(R) Active Pharmaceutical Ingredient Supplier*, (Dec. 19, 2012), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-submission-supplemental-new-drug-application.

61. Tellingly, when announcing the Chemport sNDA, Amarin revealed that adding superfluous suppliers was part of its generic-delay strategy, admitting that the "submission contributes to the planned expansion of the Vascepa manufacturing supply chain ***and is additional progress toward Amarin's goal to protect the commercial potential of Vascepa*** to beyond 2030

through a combination of patent protection, regulatory exclusivity, trade secrets and ***by taking advantage of manufacturing barriers to entry***." *Id.* (emphases added). Amarin announced that the FDA approved the Chemport sNDA in April 2013 (two years after contractually locking up Chemport). Amarin Corp. PLC, *Amarin Announces Approval of Supplemental New Drug Application for Chemport as Additional Vascepa® Active Pharmaceutical Ingredient Supplier*, (Apr. 18, 2013), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-approval-supplemental-new-drug-application.

62. Similarly, Amarin entered into an exclusive supply agreement with BASF in June of 2011 but waited a year-and-a-half to submit an sNDA for FDA approval to add BASF as an API supplier. Amarin Corp. PLC, *Amarin Announces Submission of Supplemental New Drug Application for BASF as an Additional Vascepa(R) Active Pharmaceutical Ingredient Supplier*, (Jan. 2, 2013), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-submission-supplemental-new-drug-application-0. In its press release, Amarin doubled down on its disclosure that the acquisition of exclusive supply agreements was intended to delay generic entry by "protect[ing] the commercial potential of Vascepa" and "***taking advantage of manufacturing barriers to entry***." *Id.* (emphasis added). Amarin announced that the sNDA was approved on April 30, 2013 (nearly two years after contractually locking up BASF). Amarin Corp. PLC, *Amarin Announces Approval of Supplemental New Drug Application for BASF as an Additional Vascepa(R) Active Pharmaceutical Ingredient Supplier*, (Apr. 30, 2013), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-approval-supplemental-new-drug-application-basf.

63. Similarly, Amarin submitted an sNDA for FDA approval to add Novasep as an additional icosapent ethyl API supplier in August 2013 (even thought it had announced the

Novasep agreement in 2012). The Novasep sNDA was likewise described as a way to "protect" Vascepa and utilize "manufacturing barriers to entry." These facts are summarized below:

API Supplier	Date of Exclusive Agreement	Date Amarin Filed for FDA Approval of Supplier	Date Supplier Approved by the FDA
Nisshin	February 2009	September 2011	July 2012
Equateq (BASF)	July 2011	April 2013	April 2013
Chemport	August 2011	April 2013	April 2013
Slanmhor	December 2012	May 2013	July 2014
Novasep	August 2013	August 2013	July 2014

64. Amarin worked to lock up suppliers years before it even had FDA approval to use them. To incentivize suppliers to forego other opportunities, Amarin agreed to highly lucrative terms.

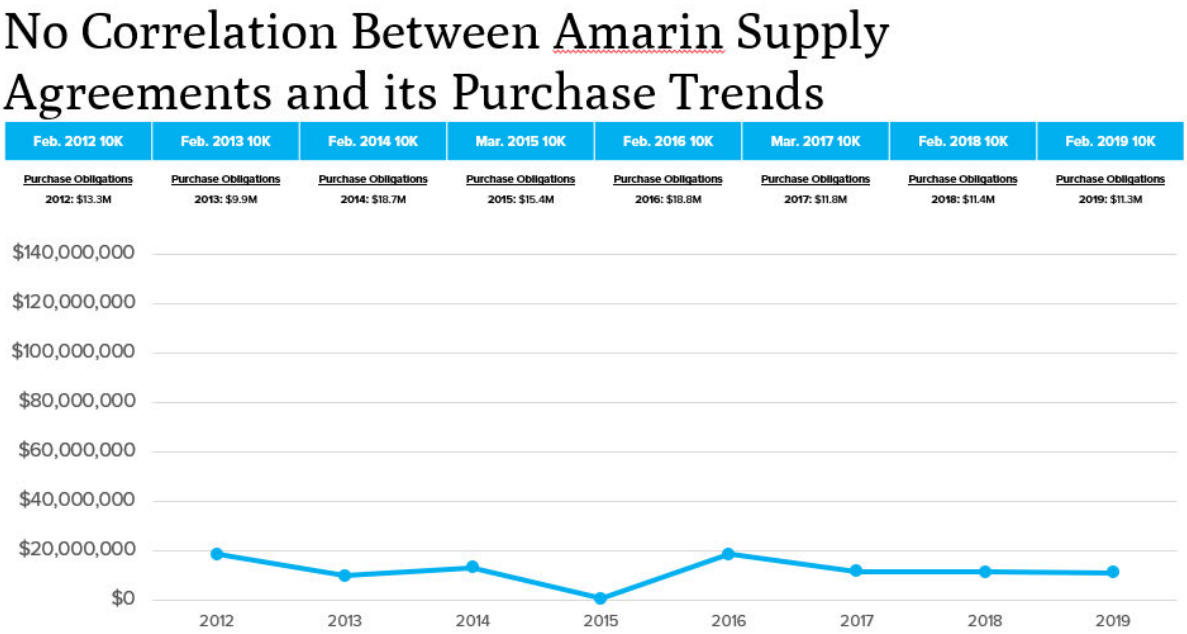
65. Amarin's agreements with these API suppliers contain expensive minimum-purchase requirements in exchange for exclusivity. For example, on information and belief, Amarin's minimum-purchasing requirements with BASF cost Amarin between $10 and $20 million per year to maintain exclusivity.

66. Some of the agreements also require Amarin to make additional payments—beyond the minimum purchasing requirements—to lock in the suppliers' exclusivity. For example, in 2011, Amarin disclosed that, pursuant to its deal with Chemport, Amarin was required to "make minimum annual purchases from Chemport ranging from approximately $7.5 to $15 million" and "make a minority share equity investment in Chemport of up to $3.3 million." Amarin Corp., *Amarin Announces Global Supply Network for AMR101*, (May 31, 2011, 2:00 AM EDT) https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-global-supply-network-amr101. Similarly, Amarin agreed to pay Equateq/BASF a $1 million commitment fee.

67. Some agreements also include provisions that protect Amarin's exclusivity and ensure that its competitors cannot access these suppliers even if Amarin could not meet the minimum purchasing requirements. To do so, Amarin took the highly unusual step of including provisions that require Amarin to make large cash payments if it could not satisfy the minimum purchase requirement for the suppliers. This was done so Amarin could maintain exclusivity with its API suppliers.

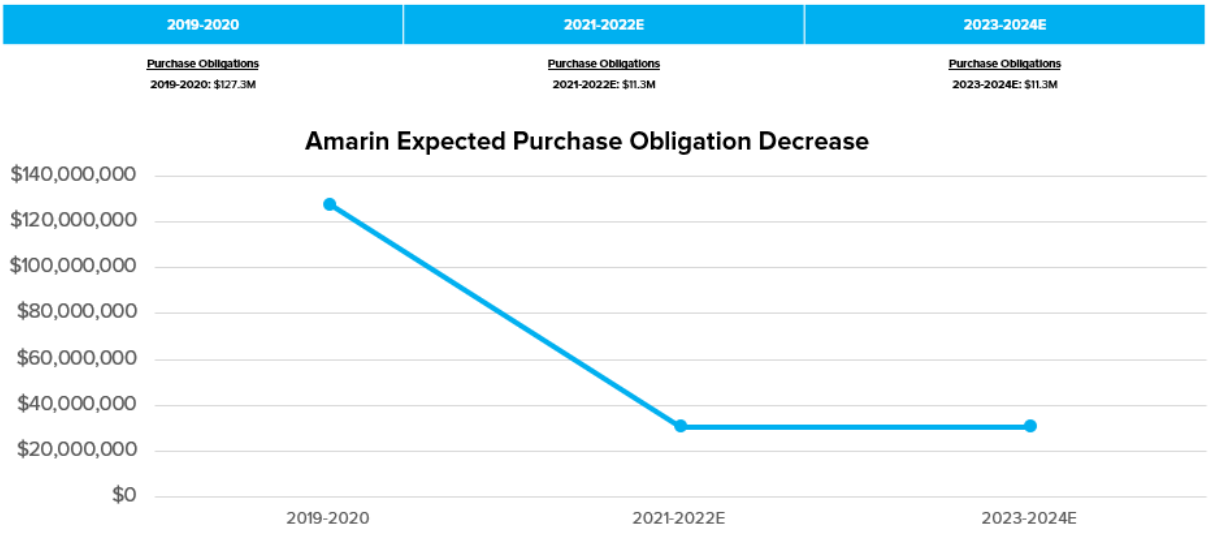
68. Amarin did not hide the intent of these agreements: the purpose of the "minimum annual purchase levels to enable [itself] to maintain certain supply exclusivity . . .," rather than to ensure sufficient capacity to keep up with demand. Amarin Corp. plc, Form 10-Q (September 30, 2018), *available at* https://www.sec.gov/Archives/edgar/data/897448/000156459018025979/amrn-10q_20180930.htm. According to Amarin's then-CEO, the company was making a concerted "effort to prevent a generic launch (if an ANDA approval is obtained)" and to erect artificial "barriers to entry" for generic competitors. *Amarin Comments on Ruling in Vascepa(R) ANDA Litigation*, GlobeNewsWire (March 30, 2020), https://www.globenewswire.com/news-release/2020/03/30/2008763/0/en/Amarin-Comments-on-Ruling-in-VASCEPA-ANDA-Litigation.html.

69. Amarin cannot explain its collection of exclusive API supply agreements as necessary to keep up with growing demand. As an initial matter, Amarin entered into many of these supply agreements before it even began recognizing revenue in 2014, and all the agreements before its revenues had even reached $81 million in 2016.



70. Moreover, Amarin did not lock up supply in anticipation of increased sales after the FDA approved a second indication in December 2019. In fact, shortly after such approval, Amarin's API purchases significantly dropped and leveled off to 2018 levels—indicating that locking up API supply was not justified by the second indication. Amarin Corp. plc, Annual Report (Form 10-K), at 87 (Feb. 27, 2019); Amarin Corp. plc, Annual Report (Form 10-K), at 91 (Feb. 25, 2020).

Amarin 2020 Expected Purchase Trends



71. Further, Amarin never announced any supply issues with suppliers or publicly disclosed any other reasons why it would increase its purchasing obligations so significantly. The chart above shows that Amarin's uptick in API purchasing is related primarily to locking up API supply, as opposed to fulfilling expected market demand.

72. Again, Amarin did not hide the success of its plan to foreclose API. It actively tracked and reported to its investors on generic companies' unsuccessful efforts to obtain API supply—having its exclusive suppliers report back: John Thero, Amarin's then-President and CEO boasted: "We have heard from various suppliers that they have been approached regarding supplying API for generic use. ***These suppliers informed us that they turned down such approaches***[.]" Amarin Corporation plc Q1 2020 Earnings Call Transcript (April 13, 2020), *available at* https://www.fool.com/earnings/call-transcripts/2020/04/13/amarin-corporation-plc-amrn-q1-2020-earnings-call.aspx (emphasis added). There would be no reason for Amarin to report such feedback from suppliers except for the fact that it was part and parcel of Amarin's strategy to stymie competition.

E. Generic Manufacturers Apply for FDA Approval to Compete with Amarin

73. In September and October of 2016, four drug companies filed applications with the FDA seeking approval to launch their generic versions of Vascepa: Roxane Laboratories, Inc. ("Roxane") and related entities (later acquired by Hikma's ultimate parent), Dr. Reddy's Laboratories Inc. ("DRL"), Teva Pharmaceuticals USA, Inc. and related entities ("Teva"), and Apotex, Inc. ("Apotex"). Roxane was the first filer.

74. Roxane filed ANDA No. 209457 on September 21, 2016, for a 1g icosapent ethyl product. After acquisition by Hikma's ultimate parent, Roxane's interest in ANDA No. 209457 and icosapent ethyl product were transferred to Hikma. For purposes of this complaint, Roxane is now known as Hikma.

F. Amarin's First Round of Unsuccessful Patent Litigation

75. Shortly after Hikma filed its ANDA, on October 31, 2016, Amarin filed a lawsuit against Hikma, alleging that its ANDA product would infringe several of Amarin's patents that were listed in the Orange Book in connection with the Very High TG Indication for Vascepa (the "Nevada Litigation").

76. As discussed above, on March 30, 2020, the Nevada court ruled in favor of Hikma and DRL and invalidated Amarin's patents, thus clearing the way for FDA approval of Hikma's ANDA (which came in May 2020) and market launch. *Amarin Pharma, Inc. v. Hikma Pharm. USA*, 449 F. Supp. 3d 967 (D. Nev. 2020).

77. Notably, the court's opinion explained that "Defendants filed ANDAs seeking FDA approval to market generic versions of Vascepa. As required by law, Defendants' ANDAs adopted the 'same' labelling as Vascepa, which at the time was only approved for severe hypertriglyceridemia. However, Plaintiffs have since won FDA approval of a second indication

for Vascepa—reducing the risk of adverse cardiovascular events . . . Defendants' current labels do not include Vascepa's new indication." *Amarin Pharma*, 449 F. Supp. 3d at 974

78. Amarin appealed the invalidity judgment to the United States Court of Appeals for the Federal Circuit ("Federal Circuit"). On September 3, 2020, the Federal Circuit summarily affirmed the Nevada court's invalidity judgment. *Amarin Pharma, Inc. v. Hikma Pharm. USA*, 819 F. App'x 932 (Fed. Cir. 2020).

79. Despite being twice rebuffed, Amarin continued litigating by requesting a rehearing, but the Federal Circuit denied that request as well. *Amarin Pharma, Inc. v. Hikma Pharm. USA*, *reh'g denied*, 2020-1723, D.I. 90 (Fed. Cir. Nov. 4, 2020). Undeterred, on February 11, 2021, Amarin petitioned for a writ of certiorari from the Supreme Court of the United States. *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.,* No 20-1119 (2021). On June 21, 2021, the Supreme Court denied the request for certiorari. *Id.*

G. Hikma's API Supply-Constraint Shock

80. Having cleared all regulatory and patent hurdles to commercializing its product, Hikma hit another anticompetitive roadblock—Amarin's exclusive API supply agreements.

81. Because of Amarin's exclusive agreements, API suppliers would not do business with Hikma, and some of them were completely unwilling to even discuss API supply with Hikma.

82. For example, when Hikma reached out to [redacted]

[redacted]

83. Similarly, Hikma reached out to [redacted]

84. Hikma also reached out to [redacted]

85. Hikma reached out to [redacted] only to learn they, too, were not an option.

86. Because of Amarin's conduct, Hikma's commercial sales were delayed, constrained, and frustrated despite Hikma's best efforts to find an alternative API supplier. This is particularly egregious because there was no legal or regulatory hurdle preventing Hikma from launching, and Hikma had been prepared to launch as soon as the requisite API became available. Moreover, to this date, more than two years after Hikma's launch, Hikma's commercial sales continue to be constrained and frustrated because of Amarin's conduct.

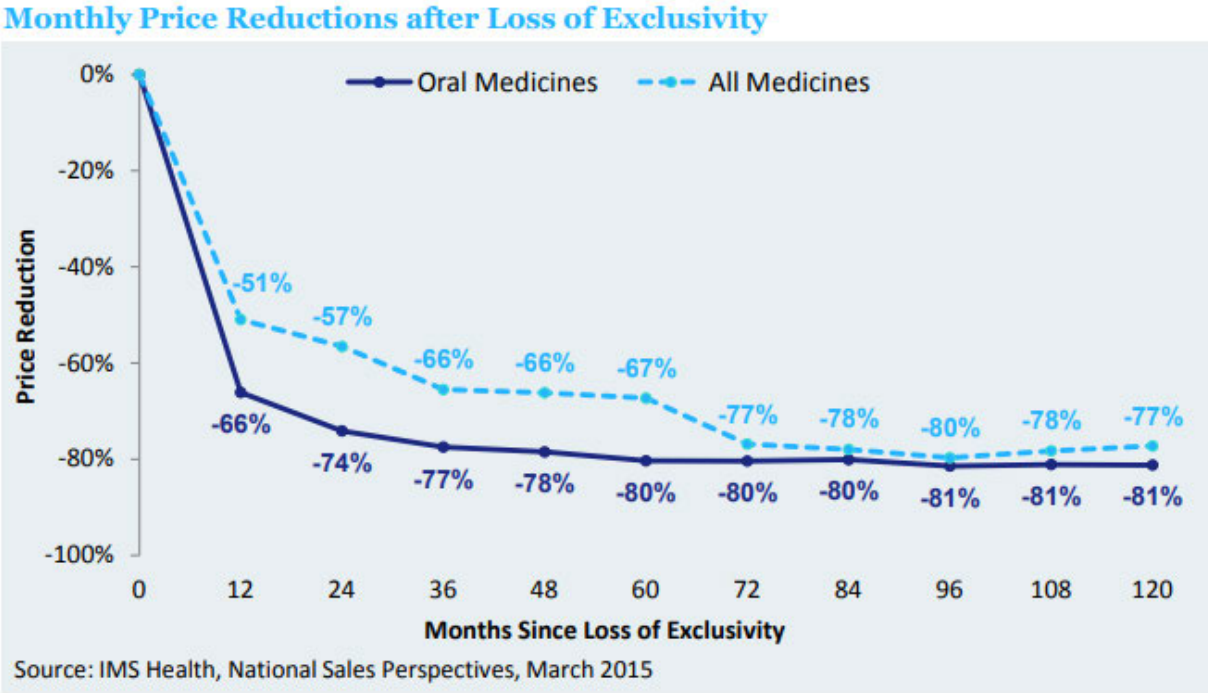
87. There was one supplier, [redacted]

88. Not surprisingly, given the supply shortage due to Amarin's API lock-up, [redacted] Having no other options, Hikma was forced to launch [redacted]

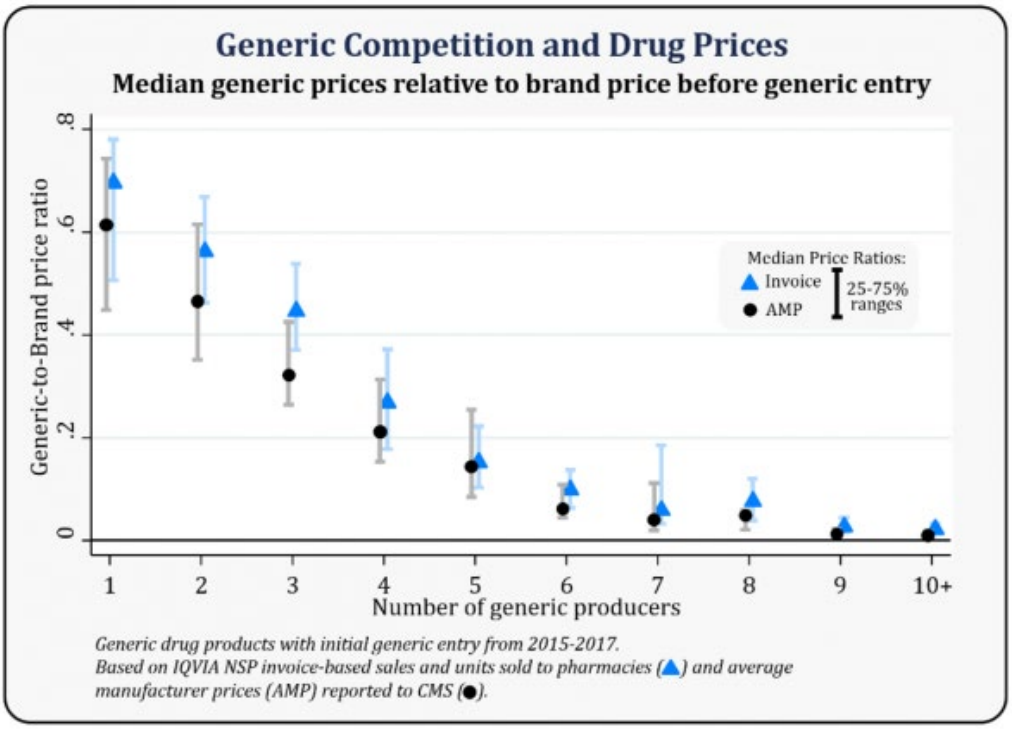
89. Despite having received final FDA approval in May 2020, Hikma finally launched in November 2020: a launch that was both *limited* due to insufficient API supply and *costly* because of Amarin's anticompetitive conduct. Hikma's commercial sales continue to be constrained and frustrated because of Amarin's conduct.

90. Upon information and belief, at the time of Hikma's launch in November 2020, Amarin's wholesale acquisition cost after rebates was less than Hikma's. Amarin has therefore been able to raise the cost of Hikma's API to the point where, at generic launch, Amarin's branded product was priced ***less than*** Hikma's generic product.

91. This is highly unusual. Absent unusual market circumstances, which do not exist here, when a generic drug manufacturer launches, the price of the drug typically decreases.



92. Furthermore, as more generic competition enters, market prices often decrease even further. Thus, consumers would enjoy lower prices, and prices decrease even further as more and more generic competitors enter the market.



93. The aberration with Vascepa can only be explained by Amarin's anticompetitive conduct. Amarin's exclusive agreements have ensured that the cost of Vascepa and its generic equivalents remains high, to the detriment of American consumers.

94. Because of these pricing issues that Amarin has created, [redacted]

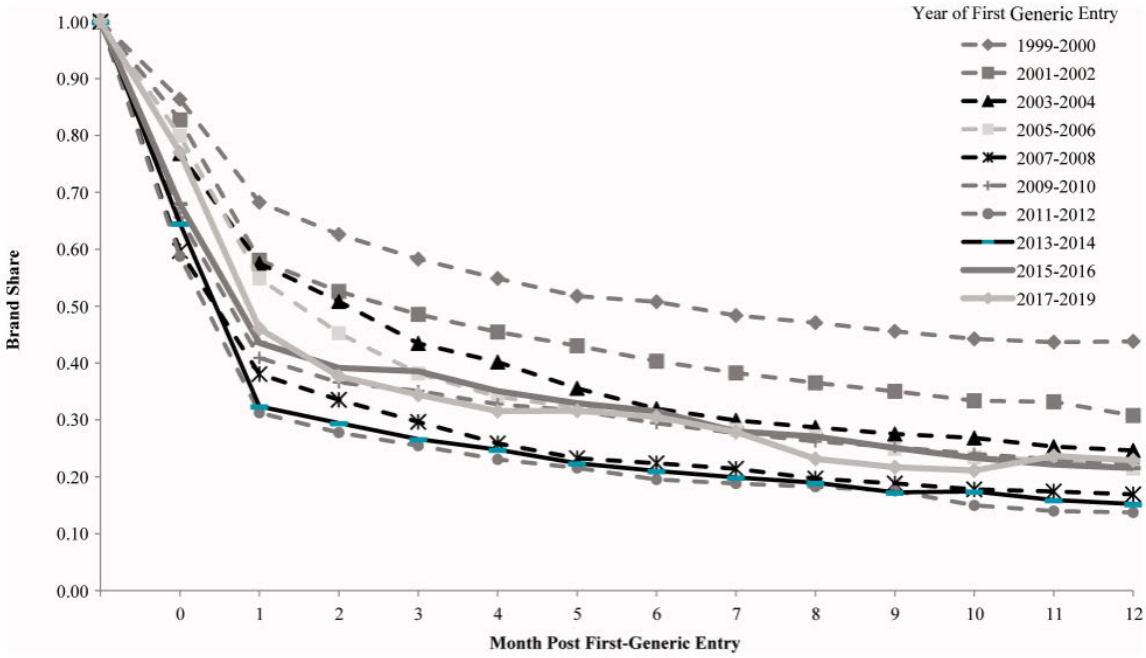
95. Amarin said that it expects "[m]arket dynamics for payors and patients are likely to be unusual relating to these generic [Vascepa] products," pointing specifically to the anticipated "***limited supply***" of the generics. Press Release, Amarin Corp. plc, *Amarin's Commercial Plans*

(June 22, 2021), https://investor.amarincorp.com/static-files/21b859d2-0823-4fd5-9c14-91678feb8447 (emphasis added).

96. Indeed, Amarin's then-CEO comforted his investors, stating that even if Hikma could find "supply capacity to support tens of millions of dollars in revenue [in the near term] . . . such level would only be a small portion of Amarin's total revenue and even a smaller portion of Vascepa's potential." Seeking Alpha, *Amarin Corporation plc's (AMRN) CEO John Thero on Q2 2020 Results – Earnings Call Transcript* (Aug. 4, 2020), https://seekingalpha.com/article/4364297-amarin-corporation-plcs-amrn-ceo-john-theroon-q2-2020-results-earnings-call-transcript.

97. This prediction has borne out. With an uncomplicated product market like the icosapent market at issue here, the usual pattern upon generic launch (as illustrated in the chart below) is that the branded drug's share quickly drops and drops further as additional generic competitors enter.

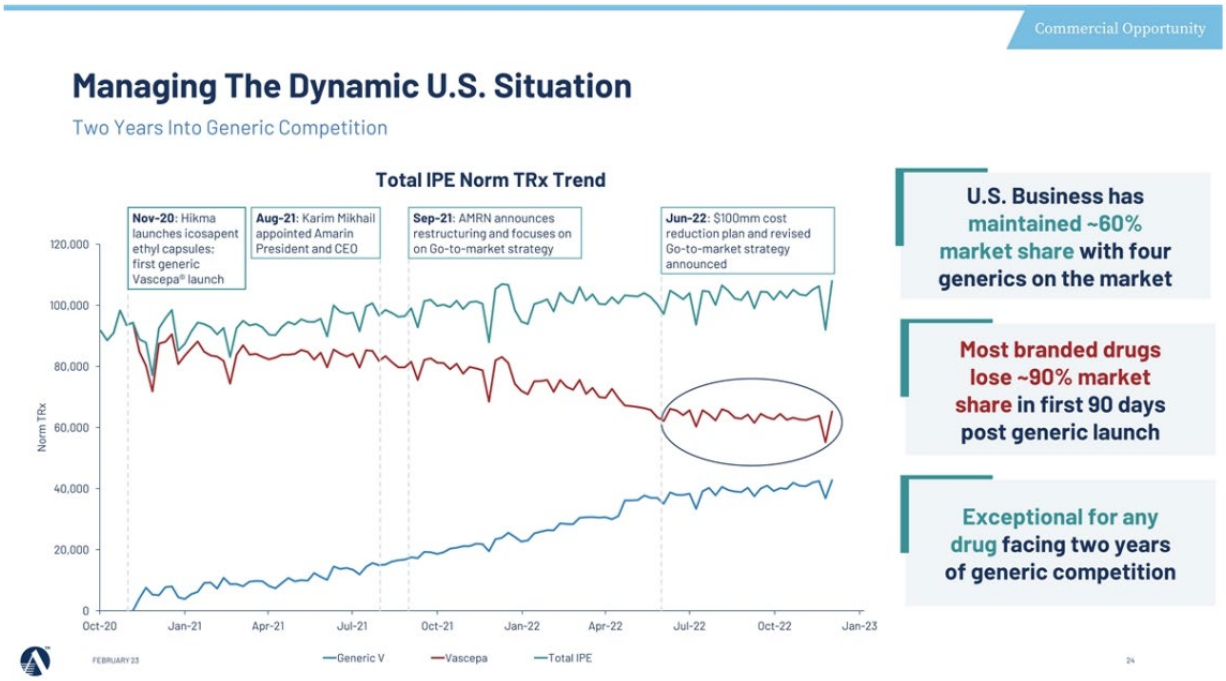
Market Share Erosion After Generic Entry



Source: Henry Grabowski et al., *Continuing trends in U.S. brand-name and generic drug competition*, 24 J. of Med. Econ. 908 (2021), *available at* https://www.tandfonline.com/doi/full/10.1080/13696998.2021.1952795#.

98. In contrast, here when Hikma launched, it captured [redacted] and Amarin maintained roughly 88% of the sales. Even after a second generic manufacturer, DRL (which filed a similar lawsuit), entered the market, Amarin's chokehold on the API supply allowed it to maintain roughly 80–85% of the sales. This unusual behavior can only be explained, as Amarin noted, by pointing to "limited supply of generics" due to Amarin's exclusive API agreements.

99. In a February 6, 2023 investor presentation, Amarin itself admitted that this trend of Amarin maintaining a large market share is "***exceptional for any drug facing two years of generic competition***." Amarin Corp., Schedule 14A at 23, (Feb. 6, 2023), *available at* https://investor.amarincorp.com/static-files/6ceab749-a8cb-46ec-92d9-79fc2878a34a (emphasis added). See below slide from Amarin's investor presentation:



100. Because Amarin has foreclosed a substantial share of the supply for icosapent ethyl API and left Hikma with limited, costly options, Hikma has [redacted]

101. [redacted]

H. Amarin's Second Round of Meritless Patent Litigation

102. A month after Hikma launched its product, Amarin filed a second patent infringement suit in the U.S. District Court of Delaware, accusing Hikma of infringing its patents for a use of which Hikma does not have FDA approval. *See Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, No. 1:20-cv-01630 (D. Del. Dec. 12, 2020), ECF 1. Pursuant to well-established practices, Hikma had filed a Section viii statement and thus carved-out the patented CV Indication from its product label.

103. Once again, Amarin lost. On January 4, 2022, the court granted Hikma's motion to dismiss, finding that Amarin failed even to state a claim that Hikma's product infringes the asserted patents. *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 578 F. Supp. 3d 642, 644 (D. Del. 2022). Amarin has appealed this ruling. *See Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, No. 23-1169 (Nov. 21, 2022), ECF 1.

MONOPOLY POWER AND RELEVANT MARKETS

104. At all relevant times, Amarin has maintained monopoly power and market power in the markets for (a) branded (i.e., Amarin's Vascepa) and generic FDA-approved icosapent ethyl drug products (collectively, "icosapent ethyl Drug Products") and (b) the purchase of icosapent

ethyl API ("icosapent ethyl API Market"). Amarin's monopoly power and market power in the market for icosapent ethyl Drug Products ("icosapent ethyl Drug Market") and icosapent ethyl API Market include monopoly power and market power over any narrower markets within them.

105. Icosapent ethyl Drug Products include AB-rated generic equivalents. FDA deems AB-rated generic equivalents to be therapeutically equivalent to the branded drug.

106. Amarin's monopoly power and market power include the ability to control prices and exclude competitors.

107. In the icosapent ethyl Drug Products Market, with respect to Amarin's ability to profitably raise prices, as shown above, a small but significant non-transitory price increase in the price of Vascepa has never resulted in a significant loss of sales, nor would a future small but significant non-transitory price increase result in lost sales. In fact, despite Amarin's consistent price increases for Vascepa over the years, the demand for icosapent ethyl Drug Products continues. As for Amarin's ability to exclude competitors, direct evidence shows that generic versions of icosapent ethyl Drug Products would have more quickly entered the market at substantial discounts to the branded version but for Amarin's anticompetitive exclusionary conduct.

108. Similarly, in the icosapent ethyl API Market, with respect to Amarin's ability to control prices, a small but significant non-transitory decrease in the purchase price of icosapent ethyl API does not and will not result in suppliers of icosapent ethyl API switching to the supply of a different API, including APIs for drugs in the same therapeutic class as icosapent ethyl Drug Products. As for Amarin's ability to exclude competitors, direct evidence shows that Amarin, through several exclusive or de facto exclusive agreements, successfully precluded generic

manufacturers of icosapent ethyl Drug Products, including Hikma, from purchasing sufficient icosapent ethyl API to commercially launch their generic icosapent ethyl drug products.

109. Amarin did not and does not need to control or influence pricing for any other pharmaceutical product to maintain its monopoly power and market power over icosapent ethyl Drug Products and the purchase of icosapent ethyl API, as there are no reasonable substitutes for either product.

110. Amarin has sold and continues to sell icosapent ethyl Drug Products at a price greater than any measurement of competitive pricing and above Amarin's marginal cost. On information and belief, Amarin has experienced atypically high profit margins for icosapent ethyl Drug Products, which have been increasing over the years.

111. In addition to direct evidence of monopoly power and market power, indirect evidence also establishes monopoly power and market power. Icosapent ethyl Drug Products exhibit high barriers to entry, including the costs of developing the product, patent protection, the high cost of entry and expansion, and regulatory requirements. Icosapent ethyl API similarly exhibits high barriers to entry, including the costs of developing the API, patent protection, the high cost of entry and expansion, and regulatory requirements.

112. Until November 2020, Amarin controlled 100% of the icosapent ethyl Drug Market. Even after Hikma launched with limited quantities in November 2020, due to the limited nature of the launch, Amarin's market share did not decrease significantly and continues to remain above 85% after Hikma's launch and above 63% through present. For example, Amarin's then-CEO commented that even if Hikma could find "supply capacity to support tens of millions of dollars in revenue [in the near term] . . . such level would only be a small portion of Amarin's total revenue and even a smaller portion of Vascepa's potential." Seeking Alpha, *Amarin Corporation*

plc's (AMRN) CEO John Thero on Q2 2020 Results – Earnings Call Transcript (Aug. 4, 2020), https://seekingalpha.com/article/4364297-amarin-corporation-plcs-amrn-ceo-john-theroon-q2-2020-results-earnings-call-transcript.

113. Similarly, until November 2020, Amarin controlled nearly 100% of the icosapent ethyl API Market because the volume of icosapent ethyl API that generic manufacturers used for their regulatory submissions is negligible compared to the commercial volume that Amarin purchased. Even after Hikma launched with limited quantities in November 2020, Hikma's inability to obtain sufficient API to support and maintain a more robust launch forced it to launch in limited quantities, gaining [redacted] of the icosapent ethyl Drug Market.

114. Icosapent ethyl Drug Products are not reasonably interchangeable with any other drugs except for AB-rated generic versions of icosapent ethyl Drug Products.

115. Icosapent ethyl API is not reasonably interchangeable with any other API.

116. The existence of other FDA-approved treatments for severe (≥ 500 mg/dL) hypertriglyceridemia has not significantly constrained Amarin, and Amarin has been increasing the prices for Vascepa over the years. For example, Lovaza is indicated for the reduction of triglyceride ("TG") levels in adults with severe (≥ 500 mg/dL) hypertriglyceridemia. Not only did Amarin not reduce the price of Vascepa upon the entry of generic omega-3-acid ethyl esters drug products in 2014, but it continued to increase Vascepa prices in the following years despite generic omega-3-acid ethyl esters drug products' price erosion over time. Even though Vascepa prices were and continue to be higher than the price of generic omega-3-acid ethyl esters drug products, demand for Lovaza and generic omega-3-acid ethyl esters drug products decreased over time whereas demand for icosapent ethyl Drug Products increased over time.

117. The existence of other purchasers of fish-oil-based API has not significantly constrained Amarin, and Amarin has maintained exclusive or de facto exclusive agreements for the supply of icosapent ethyl API with the leading suppliers of fish-oil-based API for several years.

118. Manufacturers differentiate branded drugs like Vascepa based on features and benefits (including safety and efficacy), and not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Vascepa. This is due in part to institutional features of the pharmaceutical marketplace such as the presence of insurance that bears much of the cost of prescriptions. Different patients may respond differently to different drugs and even drugs within its same therapeutic class do not constrain the price of Vascepa.

119. Unlike many consumer products where consumers are provided with a choice of functionally similar products at the point of sale and make purchasing decisions primarily based on price, the prescribing decision for prescription drugs is made by the prescriber, not consumers of these products.

120. The United States and its territories is the relevant geographic market.

ANTITRUST IMPACT

121. Amarin's anticompetitive strategy to maintain its monopoly in the icosapent ethyl Drug Market and icosapent ethyl API Market through exclusive or de facto exclusive agreements with numerous API suppliers has denied, and, unless remedied, will continue to deny consumers the benefits of full and robust generic competition for Vascepa as contemplated by the Hatch-Waxman Act. Amarin illegally maintained and extended its monopoly power through exclusionary conduct completely unrelated to its ability to compete on a level playing field.

122. Amarin's anticompetitive conduct has achieved its purpose of delaying, hindering, and frustrating generic competition to Amarin's Vascepa product. By engaging in this conduct,

Amarin effectively foreclosed a substantial share of icosapent ethyl API supply. The lack of API supply hinders ANDA filers like Hikma from robustly competing with their generic icosapent ethyl drug products.

123. This is exactly what Amarin intended to, and did, cause through its unlawful conduct. As Amarin itself has explained, "if generic companies have limited supply capacity, it would be unusual for them to sell their limited supply at a low price as it would further strain their gross margins." Amarin Corp., *What is Amarin's plan for operations now that generic versions of icosapent ethyl have launched in the United States?*, (June 22, 2021) https://investor.amarincorp.com/static-files/b042df1f-bdf1-45bb-bbee-bb22a2a9b311. During these periods of delay and constraint, consumers are deprived of lower-priced generic icosapent ethyl drug products and are forced to pay higher prices than they would but for Amarin's conduct.

124. Since generic drugs are therapeutically equivalent to brand-name drugs, generic manufacturers compete by offering their drugs at lower prices. Drugs like icosapent ethyl have an uncomplicated distribution system in which entry of a single generic typically results in steep price reductions for purchases, and entry of several generics typically drives the price down close to marginal manufacturing costs. In a market unconstrained by supply issues, generics often capture 80% or more of the market within the first six months of entry, regardless of the number of generic entrants, due to automatic substitution at the pharmacy level. *See* FTC*, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 10, 2010), https:// www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf. Automatic substitution practices allow pharmacies to fill prescriptions with generic drugs rather than branded drugs unless the prescribing physician specifically writes that a generic should not be substituted.

125. Amarin's foreclosure of the icosapent ethyl API Market, however, created a highly unusual circumstance for an otherwise uncomplicated market. By Amarin's own admission, "Amarin retained approximately 89% of the icosapent ethyl market in the first half of 2021, with approximately eight months of generic presence in the market." Amarin Corp., *Amarin Reports Second Quarter and Six Month 2021 Financial Results and Provides Business Update* (Aug. 5, 2021), https://investor.amarincorp.com/news-releases/news-release-details/amarin-reports-second-quarter-and-six-month-2021-financial. By Amarin's own admission, this situation continued, and "Amarin retained approximately 83% and 87% of the icosapent ethyl market in the three and nine months ended September 30, 2021, respectively, with approximately one year of generic presence in the market." Amarin Corp., *Amarin Reports Third Quarter 2021 Financial Results and Provides Business Update* (Nov. 3, 2021 6:00 AM EDT), https://investor.amarincorp.com/news-releases/news-release-details/amarin-reports-third-quarter-2021-financial-results-and-provides.

126. Further, had Amarin not substantially foreclosed the API supply to support a timely and robust commercial launch, generic manufacturers would not have had to [redacted] and obtain regulatory approval, thereby raising costs (and prices). This foreclosure of API supply has prevented generic competitors like Hikma from competing on the merits.

127. Amarin's anticompetitive conduct has had a direct, substantial, and adverse effect on Hikma and competition by monopolizing and maintaining monopoly power, artificially creating barriers to entry, and foreclosing competition in the icosapent ethyl Drug Market and icosapent ethyl API Market. But for Amarin's conduct, Hikma would have been able to obtain a sufficient supply of API to make a full-scale launch of its generic icosapent ethyl drug product upon receiving

FDA approval. However, because of Amarin's conduct, Hikma's launch was at limited quantities below market demand and with artificially inflated API costs. Additionally, but for Amarin's conduct, [redacted] which would have reduced the costs of launching, and therefore the price of, its icosapent ethyl product.

128. Amarin's anticompetitive conduct has impeded and continues to impede the sale of generic icosapent ethyl drug product. Amarin's anticompetitive conduct impacted Hikma's pricing and market share and, therefore, stifled robust generic competition. Unless restrained by this Court, Amarin will continue to maintain and extend its monopoly power in the relevant markets and to sell Vascepa at artificially inflated monopoly prices.

129. This conduct has harmed the competitive process and allowed Amarin to perpetuate supracompetitive prices against wholesalers, retailers, and consumers. But for Amarin's anticompetitive conduct, consumers and federal, state, and private payors would have enjoyed the benefits of lower-priced generic competition earlier. Instead, Amarin's strategies to thwart generic entry forced and continues to force consumers and federal, state, and private payors to pay monopoly rents for Amarin's branded Vascepa. The impact of Amarin's conduct is felt throughout the healthcare industry, impacting pharmaceutical competitors, healthcare providers, insurers and other direct purchasers, intermediaries, and consumers.

AMARIN'S CONDUCT HAS NO LEGITIMATE BUSINESS PURPOSE

130. There is no valid procompetitive business justification for Amarin's anticompetitive conduct, and even if Amarin offers one, it is pretextual and not cognizable, and any procompetitive benefits of Amarin's conduct do not outweigh its anticompetitive harms.

131. Amarin's multiple exclusive, or de facto exclusive, API supply contracts have no legitimate procompetitive business purpose and are contrary to industry practice. It is industry practice for a manufacturer, including a brand manufacturer like Amarin, to have one or two API suppliers, even though more may be available, because it is costly and takes time and resources to qualify and ensure quality control at the API suppliers. It is also industry practice not to have exclusive agreements with multiple API suppliers. Thus, Amarin's agreements with at least five suppliers is contrary to industry practice and economically irrational.

132. Indeed, Amarin's several exclusive or de facto exclusive agreements with suppliers since 2012 cannot be justified by the usual rationale for manufacturers to enter exclusive supply contracts—i.e., to ensure adequate supplies. The additional exclusive contracts also cannot be explained by the new 2019 indication or other market events.

133. Amarin has not been silent on its API supply. In fact, it has made repeated public statements about its API supply and the suppliers with whom it has entered agreements.[1] Amarin never once mentioned a supply issue. Indeed, Amarin boasted about its abundant supply. Amarin's public statements in January 2018 confirmed that it had "capacity to provide supply to support the potential of over $1 billion in product revenues in 2019."[2] Accordingly, without any evidence of supply concerns, Amarin has no legitimate justification for entering into the exclusive or de facto exclusive agreements with suppliers.

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[1] *See, e.g.*, Press Release, *Amarin Corp. plc, "Amarin Receives FDA Approval of VASCEPA® (icosapent ethyl) to Reduce Cardiovascular Risk*" (Dec. 13, 2019), https://www.prnewswire.com/news-releases/amarin-receives-fda-approval-of-vascepa-icosapent-ethyl-to-reduce-cardiovascular-risk300974860.html; Press Release, Amarin Corp. plc, "*Amarin Announces Patent Litigation Settlement Agreement with Apotex Inc*." (June 16, 2020), https://www.globenewswire.com/news-release/2020/06/16/2049162/0/en/Amarin-AnnouncesPatent-Litigation-Settlement-Agreement-with-Apotex-Inc.html; Press Release, Amarin Corp. plc, "A*marin Provides Update Following Ruling in Vascepa® ANDA Patent Litigation*" (Sep. 3, 2020), https://investor.amarincorp.com/news-releases/news-release-details/amarin-provides-update-following-ruling-vascepar-anda-patent.

[2] Amarin Corp. plc, *Amarin Provides Preliminary 2017 Results and Provides 2018 Outlook* (Jan. 4, 2018), https://investor.amarincorp.com/news-releases/news-release-details/amarin-provides-preliminary-2017-results-and-provides-2018.

134. Again, Amarin's own public statements make clear that Amarin entered into those agreements to lock up icosapent ethyl API supplies and prevent generic competitors from manufacturing and marketing generic icosapent ethyl drug product. In a public statement, Amarin said:

> [A]greements with our [API] suppliers include minimum purchase obligations and limited exclusivity provisions based on such minimum purchase obligations…. [T]he availability of Vascepa [API] from our suppliers to our potential competitors would make our competitors' entry into the market easier and more attractive.

Amarin Corp. plc, Annual Report (Form 10-K), at 105, F-34 (Feb. 20, 2017).

COUNT I
(Sherman Act Section I – Conspiracy)

135. Hikma repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1–135.

136. The relevant markets are the icosapent ethyl Drug Products and the icosapent ethyl API Market.

137. This claim arises under the Sherman Act, 15 U.S.C. § 1, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Amarin has violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by conspiring, combining and/or agreeing to restrain trade in the relevant markets.

138. Through the foregoing acts, Amarin, unlawfully and in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, has acted pursuant to a contract, combination or conspiracy in order to, and with the likely effect of, unreasonably restraining trade in the relevant markets.

139. Amarin knowingly and intentionally engaged in anticompetitive conduct designed to unlawfully delay and suppress the full launch and commercialization of Hikma's generic version of Vascepa and maintain its monopoly power. Amarin did this by entering into exclusive supply agreements with the leading suppliers of API icosapent ethyl. Amarin's conduct has no

procompetitive, legitimate business justification. Amarin's conduct can only be explained by anticompetitive motives to foreclose competition in the relevant markets.

140. Amarin's conduct has had a substantial effect on interstate commerce.

141. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to Hikma's business and property as well as to consumers, as set forth above. This is the type of injury the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

142. Hikma is entitled to a judgment that Amarin has violated Section 1 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Amarin's continued violations.

COUNT II
(Sherman Act Section 2 – Monopolization)

143. Hikma repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1–143.

144. The relevant markets are the icosapent ethyl Drug Products and the icosapent ethyl API Market. These markets are characterized by significant barriers to entry.

145. Amarin possess monopoly power in the relevant markets as the sole brand manufacturer authorized by the FDA.

146. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Amarin has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing the markets through exclusionary acts.

147. Through the foregoing acts, Amarin, unlawfully and in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, has used, is using and, if not restrained by this Court, will continue to use, its power in the relevant markets.

148. Through a pattern of conduct, Amarin knowingly and intentionally engaged in anticompetitive conduct designed to unlawfully delay and suppress the full launch and commercialization of Hikma's generic version of Vascepa and maintain its monopoly power. Amarin did this by entering into exclusive supply agreements with the leading suppliers of icosapent ethyl, and by ensuring generic competitors could not successfully enter the market. Amarin's conduct has no procompetitive, legitimate business justification. Amarin's conduct can only be explained by anticompetitive motives to foreclose competition in the relevant markets.

149. By its conduct, Amarin intentionally and wrongfully maintained monopoly power in the relevant markets in violation of Section 2 of the Sherman Act. As a result of Amarin's unlawful maintenance of monopoly power, Hikma has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

150. Amarin's conduct has had a substantial effect on interstate commerce.

151. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to Hikma's business and property and consumers, as set forth above. This is the type of injury the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

152. Amarin's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Hikma and consumers will suffer immediate and irreparable injury for which Hikma is without an adequate remedy at law.

153. Hikma is entitled to a judgment that Amarin has violated Section 2 of the Sherman Act; to the damages it suffered because of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Amarin's continued violations.

COUNT III
(Sherman Act Section 2 – Attempt to Monopolize)

154. Hikma repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1–154.

155. The relevant markets are the icosapent ethyl Drug Products and the icosapent ethyl API Market. These markets are characterized by significant barriers to entry.

156. Amarin possess monopoly power in the relevant markets and is the sole brand manufacturer authorized by the FDA.

157. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Amarin has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by attempting to monopolize U.S. patient market for FDA-approved pure icosapent ethyl drugs.

158. Through the foregoing acts, Amarin, unlawfully and in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, has used, is using and, if not restrained by this Court, will continue to use, its power in the U.S. patient market for FDA-approved pure icosapent ethyl drugs to attempt to monopolize the market.

159. Amarin knowingly and intentionally engaged in anticompetitive conduct designed to unlawfully delay and suppress the full launch and commercialization of Hikma's generic version of Vascepa and to attempt to create monopoly power. Amarin did this by entering into exclusive supply agreements with the leading suppliers of icosapent ethyl. Amarin's conduct has no

procompetitive, legitimate business justification. Amarin's conduct can only be explained by anticompetitive motives to foreclose competition in the relevant markets.

160. Amarin engaged in this conduct with the specific intent to monopolize the relevant markets.

161. By its conduct, Amarin intentionally and wrongfully attempted to maintain monopoly power in the relevant markets in violation of Section 2 of the Sherman Act. As a result of Amarin's unlawful attempt to maintain monopoly power, Hikma has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

162. Amarin's conduct has had a substantial effect on interstate commerce.

163. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to Hikma's business and property and consumers, as set forth above. This is the type of injury the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

164. Amarin's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Hikma will suffer immediate and irreparable injury for which Hikma is without an adequate remedy at law.

165. Hikma is entitled to a judgment that Amarin has violated Section 2 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Amarin's continued violations.

COUNT IV
(The New Jersey Antitrust Act, Sections 56:9-3 and 56:9-4)

166. Hikma repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1–166.

167. The relevant markets are the icosapent ethyl Drug Products and the icosapent ethyl API Market. These markets are characterized by significant barriers to entry.

168. This claim arises under the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9 *et seq.*, and seeks a judgment that Amarin has violated New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-3 and § 56:9-4.

169. Amarin's conduct as alleged herein constitutes monopolization, attempted monopolization, and conspiracy to monopolize, in violation of N.J. Stat. Ann. § 56:9-4.

170. Specifically, Amarin knowingly and intentionally engaged in anticompetitive conduct designed to unlawfully delay and suppress the full launch and commercialization of Hikma's generic version of Vascepa and to attempt to create monopoly power. Amarin did this by entering into exclusive supply agreements with the leading suppliers of icosapent ethyl. Amarin's conduct has no procompetitive, legitimate business justification. Amarin's conduct can only be explained by anticompetitive motives to foreclose competition in the Relevant Market.

171. Amarin's conduct as alleged herein constitutes a contract, combination, or conspiracy in restraint of trade or commerce in violation of N.J. Stat. Ann. § 56:9-3.

172. Amarin knowingly and intentionally engaged in exclusive or de facto exclusive agreements with at least BASF, Novasep, Chemport, and Nisshin to unlawfully delay the launch of Hikma's generic version of Vascepa.

173. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to Hikma's business and property and consumers, as set forth above. This is the type of injury the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

COUNT V
(Common Law of the State of New Jersey – Unfair Competition)

174. Hikma repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1–174 of its claims.

175. Through the same foregoing unlawful, predatory and anticompetitive acts as alleged, Amarin has engaged in unfair competition and unfair trade practices in violation of the common law of the State of New Jersey.

176. As a result of the foregoing, Amarin has injured Hikma in its business and property and Hikma is entitled to damages, attorneys' fees, costs of suit, and other appropriate relief.

JURY DEMAND

177. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Hikma demands a trial by jury as to all issues of right to a jury.

PRAYER FOR RELIEF

WHEREFORE, Hikma respectfully requests that this Court enter judgment in its favor and grant the following relief:

a. Permanent injunctive relief under 15 U.S.C. § 26, Fed. R. Civ. P. 65, and N.J. Stat. Ann. § 56:9-10, restraining Amarin, its affiliates, successors, transferees, assignees as well as its officers, directors, partners, agents, and employees, from continuing or renewing the

conduct, contract, conspiracy, or combination alleged or from engaging in any other conduct, contract, conspiracy, or combination with a similar purpose or effect;

b. Compensatory damages for Hikma's lost sales of generic icosapent ethyl, and profits on those sales, caused by Amarin's actions; and costs [redacted] caused by Amarin's actions in foreclosing the other suppliers;

c. Treble damages under 15 U.S.C. § 15 and N.J. Stat. Ann. § 56:9-12;

d. Pre- and post-judgment interest as available by law;

e. Attorneys' fees and costs under 28 U.S.C. § 15 and N.J. Stat. Ann. § 56:9-12; and

f. Any other further relief as the Court deems just and proper.

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By: *s/ James S. Richter*
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Dated: February 21, 2023

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the matter in controversy is the subject of two pending matters in this District: *In Re Vascepa Antitrust Litigation Direct Purchaser Plaintiffs*, Civil Action No. 21 CV 12747(ZNQ)(RLS) and *Dr. Reddy's Laboratories Inc. v. Amarin Pharma, Inc. et al.*, Civil Action No. 21 CV 10309 (ZNQ)(TJB). Hikma is not aware of any other action pending in any court or any pending arbitration or administrative proceeding related to this matter.

s/ James S. Richter
James S. Richter

Dated: February 21, 2023